

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ARROW RELIANCE, INC., dba
Darwin's Natural Pet Products,

Plaintiff,

v.

ROBERT M. CALIFF, et al.,

Defendant.

CASE NO. 2:22-cv-1057

ORDER GRANTING
DEFENDANTS' MOTION TO
DISMISS

This matter comes before the Court on Defendants' Motion to Dismiss Plaintiff's Second Amended Complaint ("Motion" (Dkt. No. 20)). Having reviewed the Motion, Plaintiff's Opposition (Dkt. No. 24), the Reply (Dkt. No. 25), and all supporting material, the Court GRANTS Defendants' Motion.

BACKGROUND

Plaintiff Arrow Reliance, Inc. (dba Darwin's Natural Pet Products ("Darwin's")), is a Washington based company that produces and sells raw pet food directly to customers. (Second Amended Complaint ¶ 7 ("SAC") (Dkt. No. 19).) The pet food utilizes raw ingredients such as

1 meat and poultry products that have been inspected and passed by the United States Department
2 of Agriculture (“USDA”) under the standards imposed by the Federal Meat Inspection Act and
3 the Poultry Products Inspection Act. (Id. at ¶ 11.) The Food and Drug Administration (“FDA”) is
4 the federal agency responsible for regulating pet food. (Id. at ¶ 9.) Plaintiff alleges that the FDA
5 has a “zero tolerance” policy as it relates to Salmonella in raw pet food. (Id. at ¶ 17.) When a
6 raw pet food product tests positive for Salmonella, the FDA asks the company to issue a recall
7 and posts a public health warning on its website. (Id. at ¶ 18.)

8 In July 2022, the FDA contacted Darwin’s when a customer’s kittens became ill after
9 mistakenly eating some of Darwin’s product that was intended for the customer’s adult cat.
10 (SAC ¶ 20.) The FDA informed Darwin’s that the kittens tested positive for Salmonella, and that
11 the FDA tested Darwin’s product and it also tested positive for Salmonella. (Id. at ¶ 20.) The
12 FDA recommended that Darwin’s conduct a voluntary recall and alert the public. (Motion at 2.)
13 The FDA also stated that if Darwin’s chose not to issue a recall and inform the public, the FDA
14 would issue its own press release to inform the public of the presence of Salmonella in the lots of
15 Darwin’s products that tested positive. (Id.) Darwin’s responded by bringing a motion for a
16 temporary restraining order and preliminary injunction before the Court, which was denied. (Dkt.
17 No. 15.) Following the Court’s denial of the temporary restraining order, the FDA issued a press
18 release cautioning pet owners not to feed their pets the lots of Darwin’s pet food that tested
19 positive for Salmonella. (Motion at 2.)

20 Darwin’s filed a Second Amended Complaint alleging four claims under the
21 Administrative Procedure Act (“APA”). (SAC ¶¶ 30-53.) Darwin’s first claim alleges that the
22 FDA compelled speech from Darwin’s when it requested Darwin’s make a public statement in
23 violation of the First Amendment, and that Darwin’s is entitled to a declaratory judgment
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pursuant to 5 U.S.C. § 706(2)(B). Darwin’s second claim alleges that the FDA did not have the authority to issue the press release and that it is entitled to declaratory relief and mandatory injunction pursuant to 5 U.S.C. § 706(2)(A) and (C). Darwin’s third claim alleges the FDA lacked adequate evidence to make the statements contained in the press release in violation of 5 U.S.C. § 706(2)(A) and (E). And lastly, Darwin’s fourth claim alleges that the FDA violated the APA when it relied on its Compliance Policy Guide in issuing the press release and that it is entitled to declaratory relief and a mandatory injunction. Defendants move to dismiss arguing that the Court lacks subject matter jurisdiction over the claims under the Federal Rule of Civil Procedure 12(b)(1), or in the alternative that the complaint fails to state a claim for relief under Federal Rule of Civil Procedure 12(b)(6).

ANALYSIS

A. Motion to Dismiss under Fed. R. Civ. P. 12(b)(1) Standard

A federal court is presumed to lack subject matter jurisdiction until plaintiff establishes otherwise. Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375 (1994). The Plaintiff bears the burden of proving the existence of subject matter jurisdiction. Stock West, Inc. v. Confederated Tribes, 873 F.2d 1221, 1225 (9th Cir. 1989). A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction can be either a facial attack or a factual one. Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004). “In a facial attack, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction.” Id. In a facial attack, the truth of the complaint’s allegations is presumed. Id. “In a factual attack, the challenger disputes the truth of the allegations that, by themselves would otherwise invoke federal jurisdiction.” Id. Here, Defendants bring a facial

1 challenge to Darwin’s Second Amended Complaint, so the Court presumes the allegations
2 asserted in the Second Amended Complaint are true.

3 Courts resolve facial attacks as they would a motion to dismiss under Fed. R. Civ. P.
4 12(b)(6). Leite v. Crane Co., 749 F.3d 1117, 1121 (9th Cir. 2014). To invoke a federal court’s
5 subject matter jurisdiction, a plaintiff needs to provide only a “short and plain statement of the
6 grounds for the court’s jurisdiction.” Fed. R. Civ. P. 8(a)(1). The plaintiff must allege facts, not
7 mere legal conclusions, in compliance with the pleading standards established by Bell Atlantic
8 Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009). See Harris
9 v. Rand, 682 F.3d 846, 850-51 (9th Cir. 2012). In determining whether the allegations are
10 sufficient as a legal matter to invoke jurisdiction, the Court must accept all plaintiff’s allegations
11 as true and draw all reasonable inferences in the plaintiff’s favor. Pride v. Correa, 719 F.3d 1130,
12 1133 (9th Cir. 2013).

13 **1. Agency Action**

14 The APA authorizes judicial review of an agency’s actions when it is prescribed by
15 statute, or it is a “final agency action for which there is no other adequate remedy in a court.” 5
16 U.S.C. § 704. Under Section 706 of the APA, a court will “hold unlawful and set aside agency
17 action, findings, and conclusions” when they are found to be, among other criteria, “arbitrary,
18 capricious, an abuse of discretion, or otherwise not in accordance with law, contrary to a
19 constitutional right, power, privilege, or immunity; in excess of statutory jurisdiction, authority,
20 or limitations, or short of statutory right, or unsupported by substantial evidence. . .” 5 U.S.C. §
21 706(2)(A), (B), (C), and (E). Because Darwin’s brings these claims under the APA and seeks
22 relief under Section 706, the Court only has jurisdiction to review them if they arise from a final
23 agency action. The FDA argues that Darwin’s cannot bring this suit under the APA because it
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1 does not challenge “agency action” within the meaning of the statute, let alone “final” agency
 2 action. (Motion at 4.) The Court agrees.

3 Agency action is limited to the specific categories defined by the APA. Norton v.
 4 Southern Utah Wilderness Alliance (“SUWA”), 542 U.S. 55 (2004). “[A]gency action” is
 5 defined to include “the whole or a part of an agency rule, order, license, sanction, relief, or the
 6 equivalent or denial thereof, or failure to act.” 5 U.S.C. § 551(13). All of these categories involve
 7 circumscribed, discrete agency actions, which are defined in the section: “rule” is “an agency
 8 statement of . . . future effect designed to implement, interpret, or prescribe law or policy. . . .”;
 9 “order” is “a final disposition . . . in a matter other than rule making . . .”; “license” is a “permit .
 10 . . or other form of permission”; “sanction” is a “prohibition . . . or . . . taking [of] other
 11 compulsory or restrictive action”; and “relief” is a “grant of money, assistance, license,
 12 authority,” etc., or “recognition of a claim, right, immunity,” etc., or “taking of other action on
 13 the application or petition of, and beneficial to, a person.” 5 U.S.C. § 551(4),(6),(8),(9),(10), and
 14 (11). Though “equivalent . . . thereof” is not defined in the APA, the Supreme Court previously
 15 found that “equivalent . . . thereof” must also be discrete “or it would not be equivalent.” Norton
 16 v. S. Utah Wilderness All., 542 U.S. 55, 62 (2004).

17 Darwin’s argues that the press release issued by the FDA amounts to a sanction or the
 18 “equivalent thereof.” (Opposition at 5-6 (“Opp”).) Darwin’s relies on three cases for the premise
 19 that a press release can, under certain circumstances, qualify as a sanction under Section 551.
 20 Trudeau v. FTC, 384 F. Supp. 2d 281 (D.D.C. 2005); Indus. Safety Equip. Assoc., Inc. v. EPA,
 21 837 F.2d 1115 (D.C. Cir. 1988) (“An agency intent on penalizing a party through adverse
 22 publicity, especially false or unauthorized publicity, might well merit a review of its action.”;
 23 Invention Submission Corp. v. Rogan, 357 F.3d 452 (4th Cir. 2004) (“Inasmuch as the APA’s
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definition of ‘agency action’ includes agency sanctions, adverse publicity might be a ‘sanction’ and therefore an agency action in certain circumstances.”) The issue in Trudeau was whether a press release issued by the Federal Trade Commission constituted final agency action under the APA. 384 F. Supp. 2d at 289. The court noted that no court has ever found a press release to be a final agency action under the APA, but the decisions in the other cases cited by Darwin’s suggest that if a press release were ever to qualify as a final agency action, one, but preferably two conditions would have to be met. Trudeau, 384 F. Supp. 2d at 289. First, there must be “evidence that the agency was intent on penalizing a private party through adverse publicity.” Id. at 289-90 (citing Indus. Safety, 837 F.2d at 1119). Second, there must be “evidence that the press release was demonstrably or concededly false.” Id. at 290 (citing Indus. Safety, 837 F.2d at 1119).

Darwin’s argues that both conditions are met in this case. (Opp. at 6.) The Court disagrees. Darwin’s argues that the FDA’s press release is adverse publicity because it reports that the products that tested positive for Salmonella represent a serious threat to human and animal health. (Opp. at 6-7.) And that the intent of the press release was to penalize Darwin’s for refusing to conduct a recall and issue its own press release. (Id. at 7.) But Darwin’s argument lacks evidence and seems to ignore the reasoning in Invention Submission Corp. In Invention Submission, the Fourth Circuit held that the Patent and Trademark Office’s conduct in engaging in an advertising campaign to warn the public about invention promotion scams was not a final agency subject to judicial review under the APA. In determining this, the Fourth Circuit discussed instances in which adverse publicity might be a sanction and reasoned:

Thus, though adverse impact alone would not necessarily make agency publicity reviewable as a sanction, an agency intent on penalizing a party through adverse publicity, especially false or unauthorized publicity, might well merit a

1 review of its action. This conclusion would be especially compelling if an
2 information release caused “destruction . . . of property,” or “revocation . . . of a
3 license.”

4 Invention Submission Corp., 357 F.3d at 458 (internal citation omitted).

5 There, the court acknowledged the test for when agency publicity may be reviewable, but
6 focused on the agency intent and the consequences that flowed from it. Here, the only fact
7 Darwin’s put forth to demonstrate the FDA’s intent is the twenty-four hour timeline to release a
8 press release and conduct a recall before the FDA issued its own press release. Darwin’s argues
9 that the adverse publicity was intended to punish it for failing to comply with the FDA’s
10 demands. (Opp. at 7.) But, as the court in Invention Submission noted, adverse impact alone is
11 not sufficient. And Darwin’s argument is highly speculative as there could be a number of
12 reasons as to why the FDA gave Darwin’s twenty-four hours to issue its own press release
13 before the FDA issued one. Absent any evidence or facts for the Court to consider, these theories
14 would remain just that. Even in drawing all reasonable inferences in Darwin’s favor, the Court
15 has no reason to conclude that the FDA’s issuance of the press release was intended to punish
16 Darwin’s. Rather, Darwin’s argument pleads legal conclusions rather than sufficient facts that
17 the Court could consider. The Court finds that Darwin’s has failed to put forth evidence that the
18 FDA’s intent in issuing the press release was to penalize Darwin’s.

19 Turning to the second condition, Darwin’s fails to demonstrate that the press release is
20 “demonstrably or concededly false.” Darwin’s argues that although dogs and cats can be infected
21 with Salmonella, the infection does not cause illness or injury and is not harmful or dangerous,
22 making the FDA’s statement otherwise false. (Opp. at 7.) Though Darwin’s asserts Salmonella in
23 animals does not cause illness or injury, that is disputed by the FDA’s press release, which states
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1 in the pertinent part that symptoms in pets include “vomiting, diarrhea (which may be bloody),
 2 fever, loss of appetite and/or decreased activity level.” (SAC, Exhibit 1 at 3 (Dkt. No 19-1).)
 3 Again, Darwin’s puts forth no evidence or facts demonstrating that the information contained in
 4 the press release is demonstrably or concededly false, it simply asserts that it is. And Darwin’s
 5 does not address the fact that this issue arose after the FDA received a report that three kittens
 6 who had consumed the product later developed diarrhea. Instead, Darwin’s focuses on the FDA’s
 7 concern over the risk to human health arising through contact with raw pet food. (Opp. at 7.)
 8 Darwin’s argues that people come into contact with meat and poultry every day and are not
 9 ignorant of the risk if the product is not handled properly. (*Id.*) Darwin’s points to the USDA’s
 10 finding that Salmonella in meat products is not injurious to health to argue that the FDA’s
 11 finding otherwise creates a situation where a poultry product with Salmonella is deemed
 12 unadulterated in one instance and adulterated in other. (*Id.*) But consumer awareness and
 13 differences between the FDA and the USDA are not relevant to the press release and fail to
 14 demonstrate its falsity. As such, Darwin’s fails to demonstrate it meets the second condition
 15 articulated in Trudeau.

16 The Court finds that Darwin’s has not shown the FDA took agency action that would be
 17 reviewable. Not only does it appear that there has yet to be a case in which a non-binding agency
 18 press release had been held to qualify as an agency action, but Darwin’s has failed to
 19 demonstrate that it meets the test for an adverse publication to qualify as a sanction. The Court
 20 finds that because the FDA’s press release does not qualify as an agency action it does not have
 21 jurisdiction to review Darwin’s alleged violations of the APA.

22 **a. Final Agency Action**

23 Even if the FDA press release qualified as an agency action, the Court finds that it would
 24 still not meet the criteria necessary to be considered a final agency action that allows for judicial

review. See Ukiah Valley Med. Ctr. V. FTC, 911 F.2d 261, 264 n.1 (9th Cir. 1990) (“finality is . . . a jurisdictional requirement). For an agency action to be final, the action must (1) “mark the consummation of the agency’s decision making process” and (2) “be one by which rights or obligations have been determined, or from which legal consequences will flow.” Bennett v. Spear, 520 U.S. 154, 178 (1997) (internal quotation omitted). “[T]he core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.” Indus. Customers of NW Utils. v. Bonneville Power Admin., 408 F.3d 638, 646 (9th Cir. 2005) (quoting Franklin v. Massachusetts, 505 U.S. 788, 797 (1992)).

In determining whether an agency’s action is final, district courts in the Ninth Circuit look to whether the action “amounts to a definitive statement of the agency’s position” or “has a direct and immediate effect on the day-to-day operations” of the subject party, or if “immediate compliance with the terms is expected.” Or. Nat. Desert Ass’n v. U.S. Forest Serv., 465 F.3d 977, 987 (9th Cir. 2006). “The finality element must be interpreted in a pragmatic and flexible manner.” Or. Nat. Res. Council v. Harrell, 52 F.3d 1499, 1504 (9th Cir. 1995) (internal quotation and citation omitted).

Here, Darwin’s claims fail because it cannot demonstrate either prong of the Bennett test. As to the first prong, the press release reveals no definitive position suggesting that the FDA has completed a decision-making process. The release merely advises consumers not to feed certain lots of Darwin’s products to its pets. (SAC, Ex. 1.) Darwin’s argues that the FDA’s decision-making process began when it received the report of the kittens becoming ill, followed by the FDA testing the product and contacting Darwin’s, and ended with the press release the contained the FDA’s definitive position that the product is adulterated. (Opp. at 10.) But, as Defendants’

1 correctly point out, the press release does not state that the FDA's position is that the product is
2 adulterated, nor does it state any other definitive position taken by the FDA. (See generally SAC,
3 Ex. 1.) And the press release does not mark a definitive end to a decision making process.
4 Darwin's argues that the FDA has not engaged in any further conduct, via an enforcement action
5 or otherwise, after it issued the statement. (Opp. at 10.) Yet, Darwin's recognition that the FDA
6 could undertake an enforcement action underscores the lack of finality. The Court finds that the
7 press release does not meet the first prong of the Bennett test.

8 Turning to the second prong, the press release does not determine any rights or
9 obligations or produce any legal consequences. Darwin's argues that the press release establishes
10 rights and obligations by declaring the product contaminated with Salmonella unfit for
11 consumption by pets, and directing customers to destroy any affected product in their possession.
12 (Opp. at 11.) Darwin's alleges that because of this statement, Darwin's customers could request
13 refunds or even file a legal action against it. In contrast, Defendants argue that while the press
14 release recommends consumers not purchase or use certain lots of Darwin's products, a
15 recommendation has no conclusive legal effect. The Court agrees with Defendants for three
16 reasons.

17 First, despite Darwin's claims that rights and obligations flow from the press release, it
18 fails to state what exactly those rights and obligations are. The press release does not require
19 Darwin's to issue a recall, contact its customers to alert them to the Salmonella, pay a fine, or
20 even inform customers of any potential rights or obligations they may have as consumers.
21 Rather, the press release "cautions pet owners not to feed certain lots of Darwin's Natural Pet
22 Products due to Salmonella" and states that "[t]he FDA recommended that Arrow Reliance, Inc.
23 voluntarily recall these products and notify that public, but the company has not done so." (SAC
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1 Ex. 1.) The press release does not include a finding that Darwin’s violated the FDCA, that
2 consumers are entitled to a refund, or that any form of legal recourse is available to consumers.

3 Second, Darwin’s argument that legal consequences flow from the press release cites to
4 two cases in support: Ipsen Biopharmaceuticals, Inc. v. Azar, 943 F.3d 953 (D.C. Cir. 2019) and
5 Sackett v. E.P.A., 566 U.S. 120 (2012). But these cases are distinguishable from the facts here.

6 In Ipsen, a pharmaceutical company brought an action against the Secretary of Health and
7 Human Services challenging the designation of pricing information that Ipsen must report to the
8 Centers for Medicare and Medicaid Services (“CMS”) for a drug that it manufactures. The issue
9 centered on whether a series of letters CMS sent Ipsen constituted a final agency action under the
10 APA. The D.C. Circuit held that the letters were final agency action permitting review under the
11 APA. Critically, the statute and regulatory scheme applicable in Ipsen required the company to
12 self-report and imposed civil penalties for false information. Ipsen, 943 F.3d at 958. The court
13 reasoned receipt of the letters significantly increased the risk of a statutory civil penalty because
14 it could be found that Ipsen knowingly provided false information in violation of the applicable
15 statute after receiving the letters. Id. at 955. As such, the court found that because the regulatory
16 scheme requires Ipsen to self-report pricing as soon as a letter was issued, each and every repeat
17 submission from Ipsen exposed it to potential civil penalties. Id. And no further or intervening
18 agency action was needed for the penalty risk and amount to start accumulating – the issuance of
19 the letter triggered it. (Id.) Thus, legal consequences flowed from each letter.

20 That is markedly different from the circumstances here where the FDA’s press release
21 does not trigger anything, it merely makes customers aware of the Salmonella and advises them
22 to get rid of any affected products they may have. And Darwin’s fails to point to specific legal
23 consequences that flow directly from the press release.

1 Sackett similar does not help Darwin's. Darwin's cites to Sackett for the premise that
2 agency determination alone was sufficient to subject the parties to additional penalties. But this
3 takes the Supreme Court's holding out of context. In Sackett, the petitioners received a
4 compliance order from the Environmental Protection Agency ("EPA"), which stated that the
5 petitioners were in violation of the Clean Water Act. The compliance order required the
6 petitioners to restore their property according to an Agency-approved plan and exposed them to
7 double penalties in any future enforcement proceedings. Sackett, 566 U.S. at 121. The Supreme
8 Court found that by reason of the order, petitioners had the legal obligation to restore their
9 property according to the EPA, and that legal consequences flowed from the issuance of the
10 order as the order potentially exposes petitioners to double penalties in enforcement proceedings
11 and limits their ability to obtain a permit from the Army Corps of Engineers. Id. at 126. As such,
12 the order had "all the hallmarks of APA finality. . ." Id. The Supreme Court did not hold that the
13 order alone subjected petitioners to additional penalties, but explicitly stated that according to the
14 Government's litigation position the order exposes petitioners to double penalties in an
15 enforcement proceeding. Id. The Court clarified that it was not deciding whether the
16 Government's position was correct, but for the purposes of assuming consequences for finality,
17 the Court accepted the Government's position as true. Id. at 126 n.2. Unlike Sackett, the FDA's
18 press release contains no findings and conclusions of law that determine Darwin's violated any
19 law. It does not require Darwin's to take any action for compliance. And it does not impose any
20 penalties or threaten any penalties if Darwin's fails to comply. This is because there is no action
21 for Darwin's to comply with. As such, Darwin's reliance on Sackett is inapposite.

22 Finally, Darwin's argues that the press release has imposed an immediate and significant
23 burden on Darwin's because it creates uncertainty over the safety of its products and impacts its
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customer relationships. (Opp. at 11-12.) Again, the Ninth Circuit has held that an agency action may be final if it “has a direct and immediate effect on the day-to-day operations” of the subject party, or if “immediate compliance with the terms is expected.” Oregon Nat. Desert Ass’n, 465 F.3d at 987. Despite Darwin’s citing to this standard, it fails to allege facts that would be sufficient to demonstrate it has met it. The FDA posted the press release to its website on August 5, 2022. (SAC ¶ 27; Ex. 1.) Darwin’s filed the Second Amended Complaint a month later on September 6, 2022. (SAC at 12.) And it filed its Opposition to the Motion to Dismiss on October 24, 2022. (Opp. at 23.) As such, almost three months passed between the issuance of the press release and the last brief Darwin’s filed in this matter. If there were “direct and immediate” effects on the “day-to-day operations” of Darwin’s, Darwin’s had the opportunity to document and properly allege them in the Second Amended Complaint and its Opposition. However, Darwin’s relies on the hypothetical and tenuous argument that the FDA’s salmonella policy casts a cloud of uncertainty over its products and that the press release “can be expected to cast a shadow over Plaintiff’s customer relationships.” (Opp. at 11-12.) Darwin’s does not contend that it has become embroiled in refund requests, lawsuits, or that it has had to change its day-to-day operations in any way due to the press release.

Taken together, Darwin’s has failed to meet both prongs of the Bennett test. The Court finds that the FDA’s press release is not a final agency action. And because a press release is not a final agency action, the Court finds this to be an additional reason that it lacks jurisdiction to review Darwin’s claims.

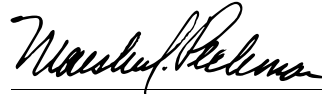
CONCLUSION

The Court finds that the FDA’s press release does not constitute agency action or final agency action for the purposes of judicial review under the APA. Because final agency action is

1 not present, Darwin's fail to adequately demonstrate the Court has jurisdiction to review its claims.
2 Since the Court finds that it lacks jurisdiction under Fed. R. Civ. P. 12(b)(1), it does not address
3 the merits of Defendants' Fed. R. Civ. P. 12(b)(6) arguments. The Court GRANTS Defendants'
4 Motion to Dismiss. A separate order will follow.

5 The clerk is ordered to provide copies of this order to all counsel.

6 Dated December 30, 2022.

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8 Marsha J. Pechman
9 United States Senior District Judge
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